

REMARKS

Claims 7-48 are pending in the present application.

The rejections of Claim 3 under 35 U.S.C. §112, second paragraph, and of Claims 1-3 under 35 U.S.C. §112, first paragraph (enablement), are obviated by amendment.

With respect to the definiteness rejection, Applicants note that this rejection was based on the recitation of “such a sequence in which one or more amino acids are deleted, substituted, or added.” This phrase does not appear in newly added claims and, as such, this ground of rejection is believed to be moot.

Turning to the enablement rejection of Claims 1-3 (now Claims 7-48). The Office has taken the position that the scope of the originally claimed invention (Claims 1-3) is not supported by an enabling disclosure (paper number 11, page 4). Applicants note that new Claims 7-48 are free from this criticism.

MPEP § 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of present Claims 7-48 would be readily apparent to the skilled artisan *without* undue experimentation. The Examiner’s attention is drawn to pages 5-7, which provides a description of the scope of homology permissible in the claimed alkaline protease. Further, the Examiner’s attention is drawn to the Table appearing on page 6 of the specification, which provide guidance for the artisan by providing a detailed listing of preferable amino acids for each Xaa within the claimed amino acid sequences (in particular SEQ ID NO:2). At pages 7-12, Applicants describe the method by which the claimed amino acid sequences may

be cloned, expressed, and isolated. Moreover, at pages 14-45, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention.

MPEP §2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In view of the specifically highlighted pages in the specification (supra), Applicants submit that they have met their burden to enable the skilled artisan to obtain an isolated alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2, wherein said isolated alkaline protease has alkaline protease activity (Claim 7).

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

Applicants request acknowledgement that the rejections under 35 U.S.C. §112, first and second paragraphs, have been withdrawn.

With respect to the obviousness-type double patenting rejection of Claims 1-3 over Claims 1 and 3 of U.S. Patent No. 6,376,227, Applicants submit herewith a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c), disclaiming the terminal part of any patent granted on the above-captioned application, which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of U.S.

Patent No. 6,376,227. Accordingly, Applicants believe that this ground of rejection is no longer at issue and should be withdrawn. Acknowledgement to this effect is requested.

The objection to the specification has been obviated by the amendment set forth herein. Applicants request withdrawal of this ground of rejection.

Finally, Applicants remind the Examiner of MPEP §821.04

...if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Upon a finding of allowability of the elected product claims, Applicants respectfully request rejoinder of withdrawn process claims.

Further, Applicants note that all pending claims ultimately depend from Claim 7 and, therefore, relate to the alkaline protease of Claim 7. Accordingly, a finding of allowability of Claim 7 would represent the point of novelty of all pending claims. As such, Applicants request rejoinder and allowance of all pending claims concomitant with allowance of Claim 7, just as the present Examiner kindly did in the parent application (U.S. 09/509,814; now U.S. Patent No. 6,376,227).

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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